International Journal of Trend in Scientific Research and Development (IJTSRD)
Volume 7 Issue 2, March-April 2023 Available Online: www.ijtsrd.com e-ISSN: 2456 – 6470

Overview of Technology Transfer in Pharmaceutical Industry

A. Ezhilarasi[1], Dr. K. Devi[2], Shantaram Nangude[3]

[1]PG Student, Department of Pharmacy, Annamalai University, Chidambaram, Tamil Nadu, India
[2]Assistant Professor, Department of Pharmacy, Annamalai University, Chidambaram, Tamil Nadu, India
[3]Sr.Principal Scientist, Archimedis Health Care Pvt Ltd, Tamil Nadu, India

ABSTRACT

This essay discusses technology transfer, its uses, and how important they are to the finding of new drugs and the creation of new pharmaceuticals. Additionally, it is necessary to improve the drug quality intended during research and development, to the finished product during production, and to ensure that consistent quality is needed. This research aimed to examine the significance of technology transfer, its components, and manufacturing unit technology transfer policies. The shift contributes to the technical advancement of succeeding companies through R&D and startup companies.

KEYWORDS: *Technology transfer, technology transfer policy, technology transfer in manufacturing unit, ich guidelines*

How to cite this paper: A. Ezhilarasi | Dr. K. Devi | Shantaram Nangude "Overview of Technology Transfer in Pharmaceutical Industry" Published in International Journal of Trend in Scientific Research and Development (ijtsrd), ISSN: 2456-6470, Volume-7 | Issue-2, April 2023, pp.346-355, URL: www.ijtsrd.com/papers/ijtsrd54023.pdf

IJTSRD54023

1. INTRODUCTION

Technology transfer, also known as the transfer of technology, is the sharing of information, technologies, skills, production techniques, manufacturing examples, and infrastructure among organisations. The beginning step and intermediate level of technology transfer are referred to. The first phase involves moving the medication delivery device from laboratories to pilot-scale manufacturing facilities. The word "intermediate stage" refers to the transition of fully operational plants and, if the product is effective, to secondary commercialization, which frequently entails movement to numerous locations across several nations.

2. Classification of technology transfer:

Technology transmission can be divided into two categories.

1. Transfer horizontally and vertically. Vertical transfer is the process by which basic research leads to clinical testing and then to the production of novel pharmaceuticals.
2. Horizontal transfer is the process of creating and applying technology used in one institution's or area's context to another institution's or area context.

Goals of technology transfer:

1. Transferring technology is a beneficial move in the creation of pharmaceutical products for commercial manufacturing.
2. All of the data gathered is used as the foundation for the process certification and ongoing product and production control strategy development.
3. Transferring information between the research and production plants, such as a method, analytical data, or product.
4. Throughout the growth of the plant, various parameters and processes are regulated to support the approved parameters.

Importance of technology transfer:

1. To organise the various information gathered during research and development in order to clarify the information required to translate technology from R&D to real production.

2. To clarify the details required to transfer current product technology between different manufacturing locations.
3. To illustrate particular steps and issues with the two kinds of technology transfer mentioned above in order to promote easy technology transfer.
4. This applies to the technology transfer related to post-marketing modifications in manufacturing facilities as well as the technology transfer related to R&D output of drug substances or drug products.

TECHNOLOGY TRANSFER POLICY

A pharmaceutical technology transfer can be defined as the transfer of scientific information, capability or a technological basis associated with a drug or a pharmaceutical procedure from a donor side (knowledge center) to a receptor side (Drug manufacturing plant) implying a positive experience learned and realised by both sides and complying all the regulatory requirement in terms of efficacy, quality and safety. As a result, the idea of outsourcing and externalisation is put into action as a chance entailing the transfer of activities out of the business as well as a halt to the use of materials and human resources. This idea or requirement is intended to address a number of weaknesses in drug development methods and should either be strengthened domestically or outsourced in this manner;

1. The framework for development management is inadequate. Executive teams lack management education strategies.
2. A lack of facilities and tools. inadequate faith in R&D Knowing how
3. Lack of exposure to GMPs, guidelines, and other quality methods, including excellent laboratory practises. realising there are no pilot experiments and random studies The study endeavour was spread out.
4. Failure to clarify goals and develop joint venture and merger plans updating and establishing tools that are accessible to all scholars.
5. Researchers' lack of adaptability and drive.
6. Poor coordination with legal standards

Facets of technology transfer:

Government laboratories to private sector, private sector to private sector within the same nation, academicians to private sector, and academic, private, and government sector to private sector

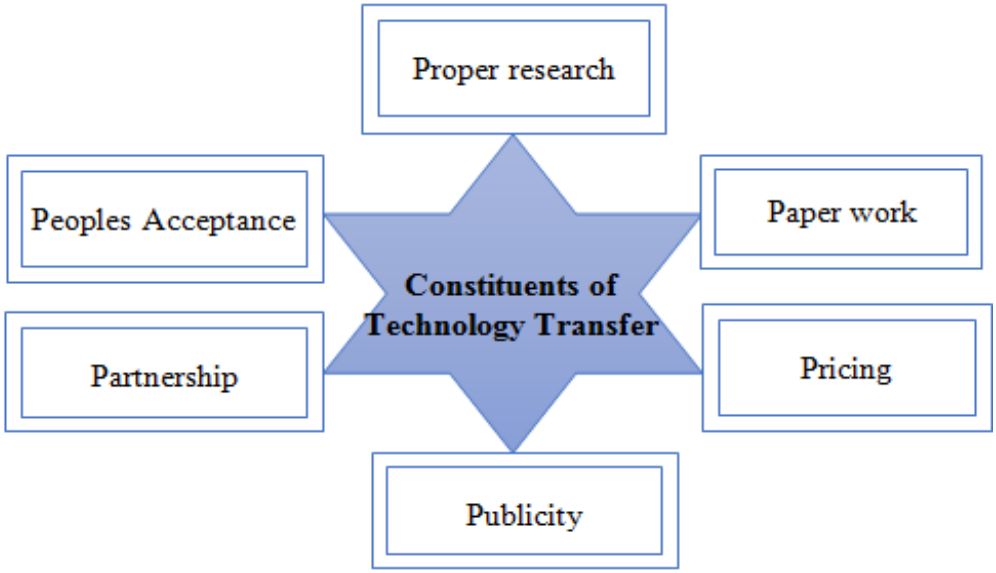
Government laboratories to private sectors: This form of technology transfer is beneficial because the government can provide government labs with excellent financial assistance and money for their research work, and the technology they create ends up in the private sectors.

A. Within the same nation's commercial industries This kind of technology transfer typically takes place as a result of insufficient regulatory understanding or a dearth of suitable financial means.

B. From academic to private sectors: Research-active academic sectors create the technology and make it accessible to for-profit businesses. Money can be conserved by private companies working together with organisations.

C. Between the academy, the business sector, and the government: In this kind of technology transfer, the government gives funding to academic organisations so they can create technology that can be applied to the industry. What makes up technology transfer?

Constituents of technology transfer



1. Appropriate study: By appropriate research, we initially mean that which has addressed issues like scale up, stability, and other real current issues, as well as that which first addressed the problem.
2. Paperwork: This includes institutional policies and regulations pertaining to IP security, licencing modalities, and other requirements that must be in place beforehand. Without these, decisions take longer and are not made fairly. For instance, in the case of X Institute, which developed excellent technology but struggled for two years before giving up because there was no direction.

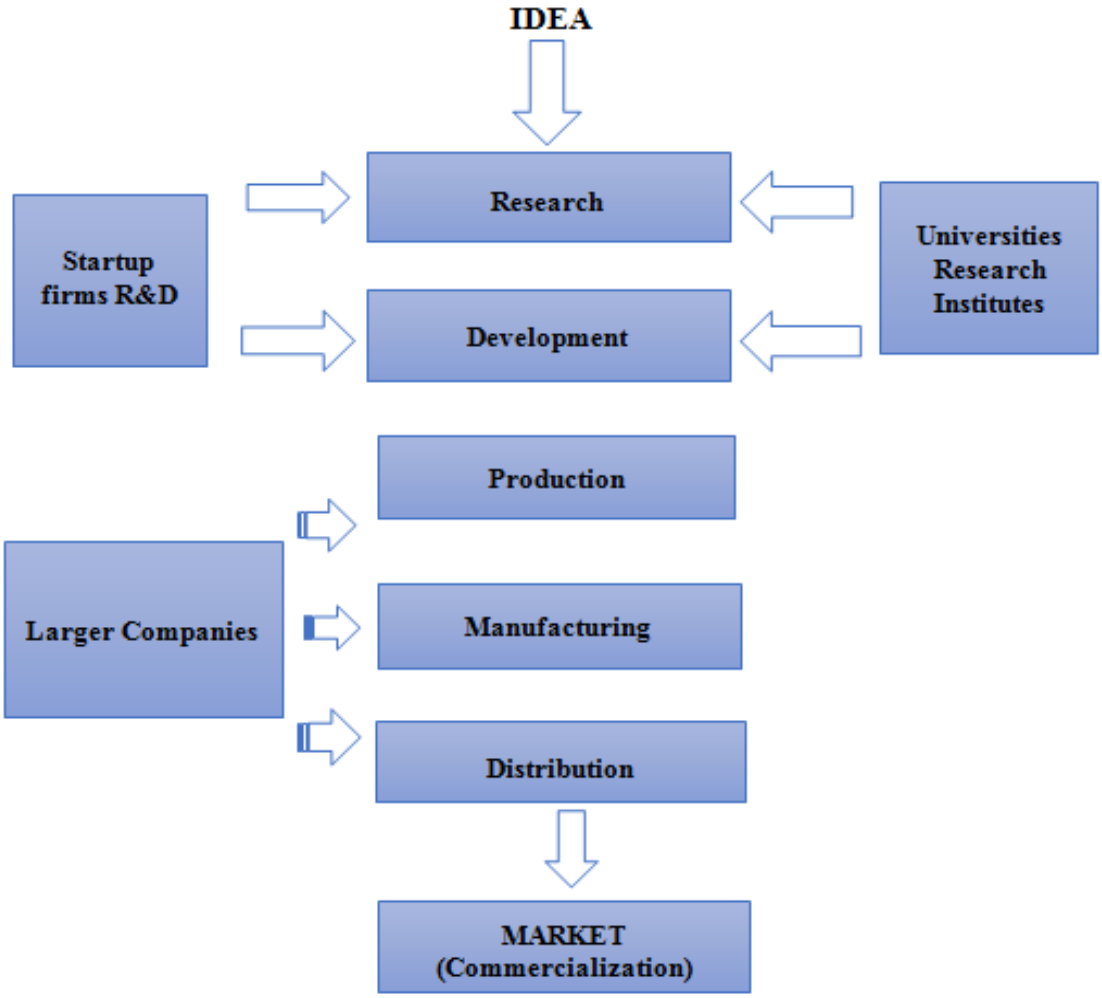
1. Pricing is the hardest and most important aspect of technology transfer.

- A price that is too expensive may turn away customers, leaving the technology unused.
- Overpricing has a negative impact on income.
- Regarding cost, there are essentially two models.

2. Market forces should determine how much a device costs.Impact of the technology, regardless of the quantity expended on its development.
3. The price paid should include all costs associated with its development.
4. exposure: It's crucial to pinpoint your target audience before approaching them, or to use tailored rather than general exposure. A common method for finding buyers is to use a specific magazine, website, emails to manufacturers, personal visits to select customers, etc.
5. Partnership: This refers to collaborating with business. Industry adopts it, produces it, and makes it accessible to society. Simply communicating the details may not be enough to guarantee your technology is effectively adopted.
6. Public Acceptance: It is useless to attempt to create a technology that the public will not use, such as because of a societal issue or a religious objection. GM products and radiation-treated veggies.

Technology diffusion across different industries

IDEA



TECHNOLOGY TRANSFER IN MANUFACTURING UNIT

Technology transfer team: The technology transfer team consist of following:

1. R&D Process technologist.
2. QA representative
3. Production representative
4. Engineering representative
5. QC representation

Technology Transfer Team and their responsibilities-Roles responsibilities the stages of technology transmission

Process technologist	➢ The main goal of transfer operations is to gather paperwork from the donor location. ➢ Perform an early evaluation of the transferred project to determine its viability, suitability for the location, and resource needs. ➢ Review the procedure's guidelines with a process technician to make sure it's capable. ➢ Take into account any potential safety risks, such as those posed by chemicals, poisonous substances, and sanitising materials. ➢ Consider the effect on regional standard operating procedures (SOPs) and the managers' and workers' training needs.
QA representative	➢ Examines paperwork for conformance with Marketing Authorization (MA) Examines analytical procedures with QC to identify tools and training needs starts the process of converting the source site to local networks ➢ The format starts or verifies regulation requirements, such as modifications to the manufacturing licence or MA if process changes are necessary, etc.
Production Representative	➢ Examines the process specifications (along with a process technician) to verify capacity/capability. ➢ Takes into account any potential safety risks, such as those posed by chemicals, poisonous substances, and sanitising Materials takes into account the effect on regional standard operating procedures (SOPs) ➢ Take into account the operators' and managers' instruction needs.
Engineering Representative	➢ Examines the apparatus requirements (with a manufacturing representative). ➢ Start the necessary engineering changes, adjustments, or component purchases. ➢ Review the effect of preventive maintenance and calibration, such as the use of more potent components or more temperature-sensitive processes, and make the necessary modifications.

1. **Technological advancement through study and development Production stage 2: record of the technology handover Technology advancement through study and development: a) Design of procedure and choosing of excipients by research and development:**

The R&D division is in charge of choosing ingredients and creating processes for the creation of the medicine.

b) R&D determines the product's specifications and quality: The product's quality must meet the requirements of an innovative product, which should be evaluated by the R and D section. Various stability studies are carried out for producing product and innovator goods to verify the specs.

- Quality verification, product creation, and research and development
- Analytical creation, confirmation, and laboratory

Commercialization and manufacturing

Transfer of technology from R&D to manufacturing

The R&D section has put into place a technology transfer document that contains all the specific details about the drug product and its formulation, including:

A master packing card, a master recipe card, or all three

d) Specifications and industry-recognized evaluation methods

Master formula card (a)

The name of the medicinal product is listed on the master formula card along with its MFCnumber, effective date, formulation strength, generic name, page number, and expiration lifeb) Master packaging card: The master packaging card contains details about the product's packaging substance, packaging style, shelf life of the packaging, and reliability of the packaging.

c) Master formula: This section outlines the directions for creating and formulating the product.The goal of the environment circumstances and dosage form development are provided in the manufacturing directions.

d) Specifications and industry-recognized test methods: These are used to determine a product's active components and excipients profile, specifications, in-process variables, and details about the final product.

Construction stage (optimization and production)
Validation tests, production scale-up, and consideration of various scaling-up factors

d) Method selection
Validation studies: Following extensive validation research, production based on the manufacturing recipe is launched. Process validation, cleaning validation, and performance certification fall under the purview of the R and section.

b. Scale up for production: This refers to the technology transfer across the creation of the procedures and pharmaceutical goods. Investigating the production environment is essential when developing the procedures. The preparation of the solid dosage form involves a number of processes. Technology transmission is put into practise before manufacturing starts.

c. Different scale-up factors should be taken into account:
For an effective technology transfer, various factors including creativity, flexibility, expense, and product quality are taken into account. Effective dialogue is a key component of achievement.

d. Methodology choice:
The technique for batch fabrication was selected using the R and D data. Granulation, mixing, compression, and coating are key stages in the transmission of technology.

Technology transmission records:
The paper contains information on technology transition to transferred parties. Every stage, from research and development to manufacturing, must be recorded, and all commitments must be fulfilled. The department in charge of quality testing is in charge of approving technology transfer paperwork.

Report on development, Technology Transfer Plan, and Report Development report: Documentation is the responsibility of the R and D division. The development report provides clarification on the specifications, test procedures, and quality design for medication compounds. This submission does not require clearance. The development report includes: • Information from the preliminary stage of development to the ultimate clearance.

Information on raw materials and components; design of manufacturing processes; modifications to critical processes and parameters; specifications and techniques for testing drug substances; accuracy of the standard range for the dissolution test and the contents impurity Records are examined

Plan for technology transfer:
A technology transfer plan comprises of detailed instructions for each individual transfer of technology, information about the technology that will be transferred, an agenda for the transfer of technology, and judgement factors for the transfer of technology. The transferring party must create the strategy prior to the transfer's execution.

Report: Only the technology transfer is finished if the data is incorporated into the technology transfer strategy. To ensure that the established criteria are fulfilled, the statistics are evaluated. The summary must be documented by both the moved parties and the transferred parties.

d. display: Following the production of scale-up quantities of the product, batches for the display are produced. In the case of display, tools and group quantities are raised, and their process is involved. They are completed in order to fill out forms for various governing organisations.

Transfer of technology implementation:
Only by transferring the technology transfer can the technology transfer be avoided. Documentation When applying technology instruction, training, and validation at locations where the transferred technology is truly put to use, both sides should work together. Verification of technology transfer results:

After the completion of technology transfer and before the start of manufacturing of the product, the transferring party should verify with appropriate methods such as product testing and audit that the product manufactured after the technology transfer meets the predetermined quality and should maintain of the results.

Factors affecting the spread of technology
1. ethical production and company practices
2. The possibility of competing pricing
3. Planning strategically
4. A robust business and advancement
5. Open and effective control
6. Possibilities for emergency supplies

Technology transfer from R&D to production:

S. No	Giving site	Receiving site
1	Provide latest source documentation	Executive protocol (analytical method)
2	Latest specifications (internal or registered)	Qualified facility and equipment or instrument
3	Provide process (technology transfer)	Set up system
4	Protocol / report (Analytical report method)	Set up training program

Three steps make up the technology transfer procedure, or "wings," as it is also known.

Production and quality assurance

Documentation (iii).

1. Transfer of technology production:

The sending unit and recipient unit prepare a product transfer protocol together to convey details about the made product. The technological proficiency of the staff and the production facility's capacity to manage the entire process efficiently determine how much information is provided about the product.

A starting point:

Materials that are used to produce transmitting units and receiving units should be consistent, and raw material properties that can change product quality should be recognised.

Pharmaceutically active ingredients:

The transmitting unit provides the drug master file as well as additional API-related information, which contains the following.

Physical properties of the substance, such as bulk density and tap density, Water activity, and the spectrum of moisture content Sterility The Bio burden Entotoxins are necessary. Required dissolution characteristics Particle size, solubility, and PH of the solution. The material's supply network. Additional data, such as light and thermal exposure.

Excipients: Excipients also significantly affect the finished product, so the transmitting unit should provide the recipient unit with their comprehensive information. It might contain the following details:

- Physical characteristics such as bulk density and tap density; • Moisture content range; • Melting point; • Bio load, lipopolysaccharide, and sterility as needed; • Viscosity to the materials; • Flow chart of the manufacturing to the materials;

Ion strength, pH solution, solubility, particulate size distribution, and specific gravity, as well as the manufacture and supply network of the substance, are all factors to consider. the criteria for BSE and TSE compliance

- Light, heat, and wetness reactivity as well as MSDS.

Process-related content

Receiving unit and have the physical definition, in-process management, and specification of the production process in depth.

Produced to completion:

After a successful transfer of technology, the history of the product's advanced features should be given for future enhancement, development, or product optimisation. The accepting unit should be provided information on the climate, health, safety, and welfare. It ought to be given to the recipient device as well. Additionally,

details on product quality assessment, stability, validation, and production environment requirements should be included. Before taking the validation batch, trial batches are taken at the accepting receipt unit to establish the production process's capacity and manufacturing specifications.

Packing procedure: All data pertaining to packing should be transmitted along with the production procedure. The specifics of the foils, receptacles, and closures are included, along with other pertinent data like design labelling and sketches.

Cleaning procedure: Adequate procedures must be followed in order to avoid contamination of medicinal goods. In production, it can lessen the chance of cross pollution. The transmitting unit should provide the necessary information, such as the current cleaning procedure, solubility of all materials, therapeutic dosage, toxicity of the API, cleaning agent, and recovery study, while the receiving unit should verify the cleaning procedure.

Manufacturing site: The sending entity should send any relevant facility design details.

The layout of the facility, the buildings, the utility services, the danger of fire, the environments for workers' health and safety, and environmental concerns should all be included in the premises.

- Equipment: For the sending section, an inventory of necessary items along with their models should be given. The guides, drawings, cleanings, working, and upkeep instructions should all be included. Equipment IQ, OQ, and PQ should be carried out by the reception section.
- 2) Quality assurance: application of analytical techniques
- The creation of analytical methods is necessary for testing the produced goods, and accurate analytical methods can speed up the testing process. Receiving unit implementation of the method analysis for finished product, raw materials, packing materials and cleaning residues before the starting of the process validation analytical method transfer protocol should be prepared including responsibilities of both sending unit and receiving unit, specification of product, acceptance criteria, interpretation of results, report format, reference standards and deviations during analysis. The researchers should receive instruction, which should be recorded in their training records.
- 3) Documentation: Each stage of the technology transfer procedure should be recorded, and a summary report with the transfer's conclusion should be created.
- During the process, any discrepancies should be noted and addressed by taking the proper action. The following paperwork should be ready for an effective tech move.
- Protocol for Technology Transfer; • Reporting Protocol for Facility Qualification
- Protocol for equipment certification and report
- Protocol and summary for process evaluation
  - Report and approval procedure for cleaning
- Methods for removing obstacles to technology transmission
- Commercializing publicly-funded innovations, research tools, and public sector operating independence, and web access and scholarly publications
- Inadequate financing in critical areas and potential accords d) National security concerns and limitations on experts in specific technologies e)
- f) Agreements on cooperative study g) Potential treaty on science access
- Commercializing publicly supported technologies is envisioned as giving organisations that receive public research funding the ability to secure and make use of patents on discoveries made during research.
- b) Research instrument patents and public sector freedom to operate: Patents occasionally make it challenging for public researchers to conduct their research or make the results of their work accessible. It is made worse by some publicly supported research laboratories' propensity to refrain from using patented technology without authorization, even in countries where no applicable patents are in effect.
- c) Web access and scientific publication: Scientists in emerging nations faced severe challenges as a result of limited access to scientific publications.
- d) National security concerns and export limits on specific technologies: International regulations intended to safeguard national security and stop the spread of crucial technologies also impose restrictions on the

movement of technologies. Lack of money for crucial areas and potential treaties; Some crucial study areas for the developing world receive insufficient support.

- e) Cooperative research agreements: By establishing co-operative research agreements that are tailored to achieve particular objectives, international funding for public sector research may be stimulated. It would seem more practical to concentrate efforts on technologies that have a major positive societal impact on developing countries.
- f) Potential treaty on scientific access: An international treaty on knowledge and technology access has also been proposed, and it would be discussed using the same reciprocity that is typically used in international trade talks. The notion is intended to be non-zero-sum in the sense that, similar to free trade in commodities, free trade in scientific ideas helps everyone, and such agreements could be made both individually and multilaterally. The following were different phases of formulation creation.
  - Preformulation research
- Scale up: 1/10th of X or 0.1 M, whichever is the utmost. Bench scale: 1/ 1000th of X. Lab scale: 1/ 100th of X.
  - business Where, X - ultimate batch quantity for business volume.
- Changes to the authorised marketing authorisation (MA) can pose the biggest challenge to the transfer deadlines, according to regulatory problems in technology transfer.
  - The majority of production facilities no longer serve a single market, and in places where centres of excellence have been established, a single facility may serve the entire world.
  - The regulatory procedure can take anywhere from 30 days to 12–14 months for even the most basic action, such as filing a site move. The choice to make few (if any) changes to the moved product or procedure is fundamental to the transfer process. The regulatory complexity and related delays grow along with the degree of change.

Guidelines from the WHO on technology transfer:

The preponderance of pharmaceuticals undergo site transfers at every stage of their life cycles, including product research, manufacturing, and market introduction. This WHO recommendation will be applied to the production of pharmaceutical active components, the making and packaging of pharmaceutical finished goods, as well as the conducting of analytical testing. Technology transfer requires a strategy and paperwork that makes use of a qualified and well-experienced individual working in the quality system and provides evidence of data for all research, manufacturing, and quality control areas. Typically, a receiving unit, a transmitting unit, and the unit that manages the procedure are present. The WHO recommendations for technology sharing are shown in Fig.

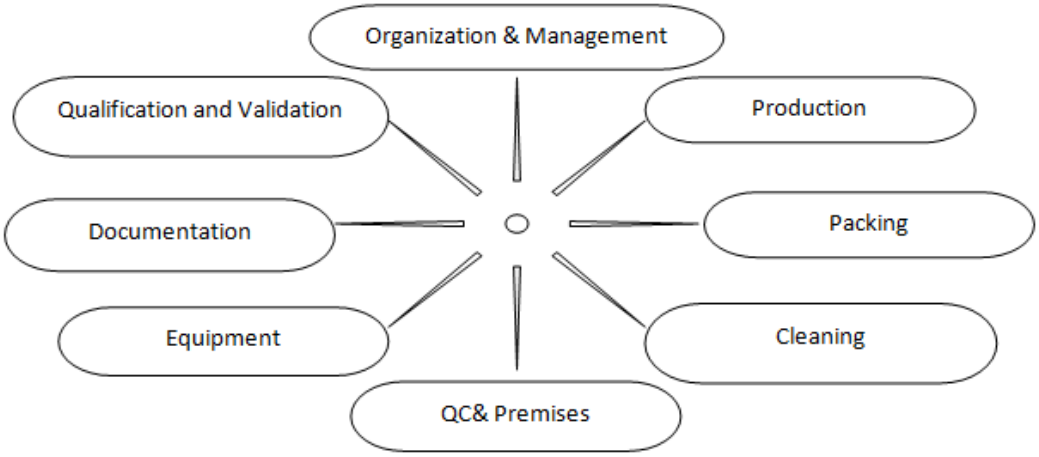
The following areas at the transmitting unit (SU) and receiving unit (RU) are covered by the WHO guidelines:

- The transfer of drug product production, packing, and cleaning procedures.
- The transfer of analytic techniques for quality assurance and control.

Evaluation of competencies and instruction Evaluation of the setting and machinery

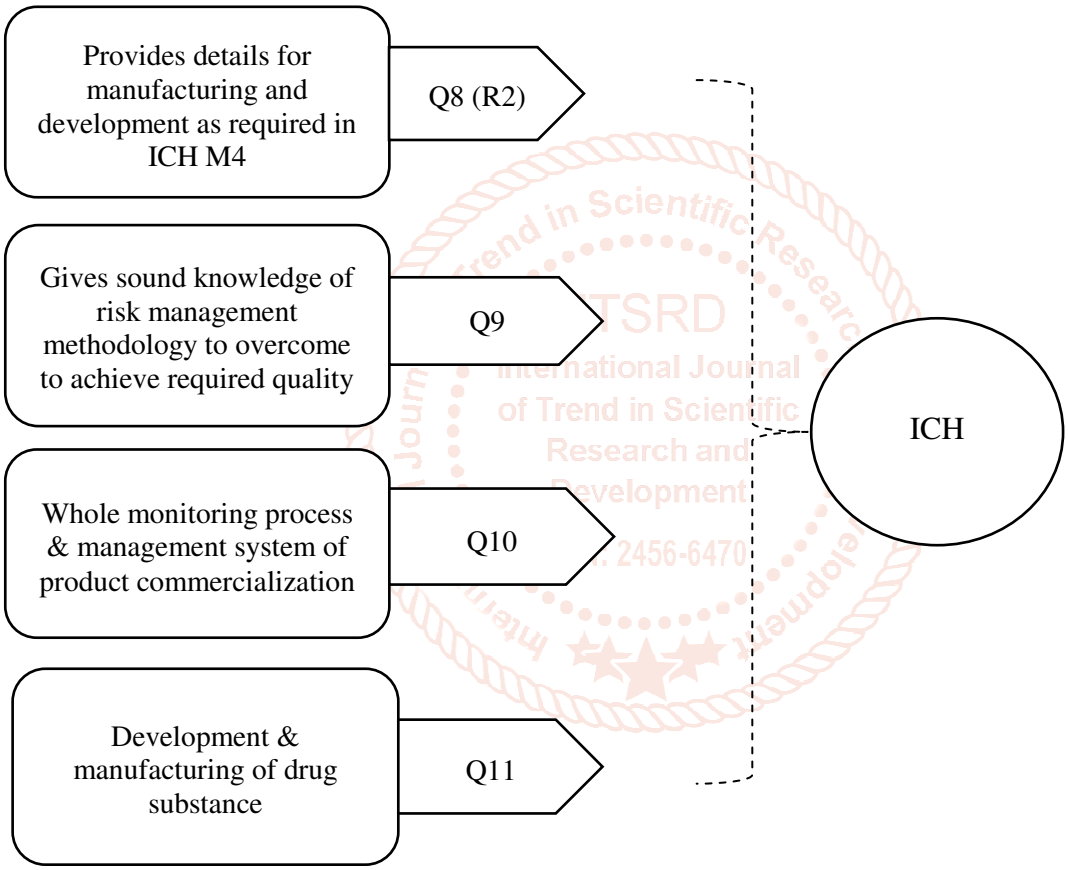
- Recording of all the info Control and management of the technology transition
- The evaluation and verification of all technological procedures.

WHO Guidelines on Technology Transfer



The role of ICH guidelines in technology transfer is as follows:

- Technology transfer includes knowledge transmission, science, and risk-based principles, including ICH Q8, Q9, Q10, and Q11 as well as skilled procedures to safety-evolving commercial requirements.
- Depending on the type and scope of the transfer, these specify the requirements for effective technology transfer and offer guidance on how to perform it.
- The goal of technology transfer activities is to transfer process and product knowledge between research and manufacturing sites as well as within production sites in order to realise a product, according to ICH Q10 guidelines.
- On the base of this data, the product is manufactured, monitoring strategies are used, the processes are validated, and continuous development is carried out.
- To guarantee a successful technology transfer, pharmaceutical companies ought to create a collaborative improvement team must have the required qualification, knowledge, and skills to affect the transfer, originate a written controlling method to concentrate attention on crucial points in the process and equipment, review the process for inputs/outputs that might affect the quality of the product.



CONCLUSION:

Technology and information transfer are required to maintain medication quality while it is being produced. Fortunately, technology transfer may be studied if a receiving area can consistently replicate the procedure. The plan, the individual in question, and the manufacturing method are the three key topics to be covered through the body technology transfer. Pharmaceutical companies look for technology transfer possibilities to lower the risk of failure, lower expenses, and to reduce risk because technology transfer provides a way to lower the cost of drug research and development. The technology team collaborates to produce superior results in the first and subsequent trials, which results in the prior license, the earliest debut, and a larger market share.A recipient unit can regularly replicate the transferred product, process, or method against a predetermined set of specs if this is agreed upon with a transmitting unit and/or a creating unit. This is a requirement for effective technology transfer. Licensing is a technology transfer strategy that has acquired traction in the pharmaceutical business and allows pharmaceutical companies to support R&D. Technology migration is a complicated problem that should be handled holistically. Therefore, knowledge and information should be shared evenly and constantly from one party to another. This will aid in the production of the product and, ultimately, the growth of both parties. Technology transfer in the

pharmaceutical industry refers to the action of transferring the data and technologies required to realise the standard of drug formulation throughout manufacturing. The technology transfer implies ongoing information sharing between the parties to sustain product production, not just one-time actions done by the transferring party towards the transferred party.

Reference:

[1] Allamneni Y, Chary PD, Kumar sc, Rao VB. Technology transfer process in pharmaceutical industry: An overview of / pharma dutor; 2020. Available from: https//www.pharmadutor.org/articles/overview of technology transfer in pharmaceutical industry. (Last accessed on 03 Oct 2020).

[2] Anuj A and Bhuvanesh KS: A Review on the importance of technology transfer in pharmaceutical industry. An international journal of pharmaceutical industry. An international journal of pharmaceutical research 2016; 1 (4): 141-42

[3] Bharat bhusan, Ujjwalnautiyal, senthilkumar, Abu Bakar, A Review of technology transferin pharmaceutical industry; International journal of pharmaceutical and medical research; 2019; 2(3); 94-99.

[4] Biruk A, Biruk Abate, Technology transfer in pharmaceutical industries through product development and scale up approaches: challenges and oppurtunities for developing countries, International Journal of Engineering technology and advanced Engineering.2016; 6(7): 232 -243.

[5] G.M. Pavithra, manoranjith, S. Nagalakshmi: An overview of technology transfer as a regulatory aspect vol.13 Issue 2020

[6] James Swarbrick, James C Boylan: Encyclopaedia of pharmaceutical Technology; Technology transfer considerations for pharmaceuticals, Vol.1, 3rd edition; 2016.

[7] Manish SM, Bharat p, Yakub S, Technology transfer in pharmaceutical industry, international journal of pharmaceutical and medical research, 2018; 2(3); 95-96

[8] Manu C, Vishal NG, Review on technology transfer in pharmaceutical industry, international journal of current pharmaceutical Quality assurance, 2016; 7(1):7-14.

[9] Patil RP, Technology transfer in pharmaceutical industry: objective, Issues and policy approaches, Int J Pharm Res Dec, 2017; 2(17); 7-14.

[10] Popat. B. Mohite and sachin V. sangle: International journal of advances in pharmaceutics 2017; A Review on technology transfer in pharmaceutical Industry.

[11] Rajesh dumpala and chiragpatil: Review on Technology Transfer in pharmaceutical industry; Facts and steps involed (Impact factor 6.222) AUG 2020.

[12] Ripalsuthar, Jignesh s. shah, Review on technology transfer as a regulatory aspect with inclusion of ICH guidelines; Asian journal of pharmaceutical technology and innovation. 05(23), 2017; 32-40.

[13] Shalini: An overview of technology transfer of pharmaceutical industry; (vol: 11) last accessed on FEB 2020.

[14] Singh A, Aggarwal G. Technology transfer in pharmaceutical industry: A Discussion. International journal of pharmaceutical Biosciences, 2019; 2(4):123-129.

[15] Waghmare YS and mahaparale SP: The important role of technology transfer in the pharmaceutical industry – A Review. World Journal of pharmaceutical Research 2017; 6(9):310-29.